K062876

Lifecore Biomedical, Inc.
Special 510(k) Premarket Notification
PrimaConnex® Ceramic Abutments

NOV - 1 2006

510(K) SUMMARY
[As required by 21 CFR 807.92(c)]

1. Submitter's Name and Contact Person

Lifecore Biomedical, Inc. 3515 Lyman Blvd Chaska, MN 55318	Brian Smekal Regulatory Affairs Specialist Ph: 952-368-6306; Fax: 952-368-4278

2. General Information

Trade Name	PrimaConnex® Ceramic Abutments
Common Name	Ceramic Abutments
Classification Name	Endosseous Implant Abutment
Identification of Predicate Devices	Esthetic Contour Straight Abutments for the PrimaConnex Internal Connection Implant System, Lifecore Biomedical (K051614) PrimaConnex Ceramic Copings, Lifecore Biomedical (K060530) Astra Tech Implants – Dental System Ceramic Abutment, Astra Tech, Inc. (K023631)

3. Device Description

PrimaConnex Ceramic Abutments are intended for use in conjunction with the PrimaConnex Internal Connection Implant System in partially or fully edentulous mandibles and maxillae, in support of single or multiple-unit cement retained restorations.

4. Intended Use

PrimaConnex Ceramic Abutments are intended for use in conjunction with the PrimaConnex Internal Connection Implant System in partially or fully edentulous

mandibles and maxillae, in support of single or multiple-unit cement retained restorations.

5. Substantial Equivalence Comparison

Summary of how the **PrimaConnex Ceramic Abutment** is substantially equivalent to the **PrimaConnex Esthetic Contour Abutment** (K051614):

- Have the same intended use,
- Incorporate the identical design,
- Have the same shelf life, and
- Are packaged and sterilized using the same materials and processes.

Summary of how the **PrimaConnex Ceramic Abutment** is substantially equivalent to the **PrimaConnex Ceramic Copings** (K060530):

- Incorporate the identical biocompatible material,
- Are packaged using the same materials and processes.

Summary of how the **PrimaConnex Ceramic Abutment** is substantially equivalent to the **Astra Tech Implants – Dental System Ceramic Abutment** (K023631):

- Have the same intended use,
- Incorporate the identical biocompatible material,
- Incorporate the same fundamental scientific technology.

In summary, the PrimaConnex Ceramic Abutment described in this submission is, in our opinion, substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Mr. Brain Smekal
Regulatory Affairs Specialist
Lifecore Biomedical, Incorporated
3515 Lyman Boulevard
Chaska, Minnesota 55318

NOV - 1 2006

Re: K062876
Trade/Device Name: PrimaConnex® Ceramic Abutments
Regulation Number: 21 CFR 872.3630
Regulation Name: Endosseous Dental Implant Abutment
Regulatory Class: II
Product Code: NHA
Dated: October 20, 2006
Received: October 24, 2006

Dear Mr. Smekal:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number: K062876

Device Name: PrimaConnex® Ceramic Abutments

Indications for Use:

PrimaConnex Ceramic Abutments are intended for use in conjunction with the PrimaConnex Internal Connection Implant System in partially or fully edentulous mandibles and maxillae, in support of single or multiple-unit cement retained restorations.

Prescription Use X AND/OR (Part 21 CFR 801 Subpart D)

Over-The-Counter Use _____ (21 CFR 807 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED

Concurrence of CDRH, Office of Device Evaluation (ODE)

Division of Anesthesiology, General Hospital, Infection Control, Dental Devices

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